CLAIMS

1. A pharmacologically active combination, having utility in treating insomnia patients, which comprises:

(a) at least one first active ingredient selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; and

(b) at least one second active ingredient selected from nicotine and nicotine receptor agonists.

2. A pharmacologically active combination according to claim 1, which is characterized by at least one of the following features:

(i) it comprises also at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and the dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled, sustained or prolonged release formulation;

(iv) it is in a depot form which will release the said active ingredients slowly in the body, over a preselected time period;

(v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier and/or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

3. A pharmacologically active combination according to claim 2, which is in the form of dosage units, wherein each dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025-100 mg.

4. A pharmacologically active combination according to claim 3, wherein said amount lies within the range of 0.25 to 50 mg.

5. A pharmacologically active combination according to claim 4, wherein said amount lies within the range of 0.5 to 40 mg.

6. Use of at least one first active ingredient (a) selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, in the manufacture of a first medicament which alleviates at least one of the following adverse effects which occur in the patient in the course of nicotine replacement therapy, namely, impairment of the quality of sleep, impairment of cognition and impairment of memory, wherein said patient may optionally be receiving simultaneously a second medicament comprising at least one second active ingredient (b) selected from nicotine and nicotine receptor agonists.

7. Use according to claim 6, wherein each of said medicaments is characterized respectively by at least one of the following features:

(i) it comprises also at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and the dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled, sustained or prolonged release formulation;

(iv) it is in a depot form which will release the said active ingredients slowly in the body, over a preselected time period;

(v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier and/or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

8. Use according to claim 7, wherein said medicament and a second medicament are respectively in the form of dosage units, wherein each dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025-100 mg.

9. Use according to claim 8, wherein said amount lies within the range of 0.25 to 50 mg.

10. Use according to claim 9, wherein said amount lies within the range of 0.5 to 40 mg.

11. Use of at least one first active ingredient (a) selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, in the manufacture of a first medicament which in the presence of a second medicament as defined below alleviates, in patients other than those receiving nicotine replacement therapy, at least one of the following adverse effects, namely, impairment of the quality of sleep, impairment of cognition and impairment of memory, wherein said second medicament comprises at least one second active ingredient (b) selected from nicotine and nicotine receptor agonists.

12. Use according to claim 11, wherein each of said medicaments is characterized respectively by at least one of the following features:

(i) it comprises also at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and the dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled, sustained or prolonged release formulation;

(iv) it is in a depot form which will release the said active ingredients slowly in the body, over a preselected time period;

(v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier and/or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

13. Use according to claim 12, wherein said medicament and a second medicament are respectively in the form of dosage units, wherein each dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025-100 mg.

14. Use according to claim 13, wherein said amount lies within the range of 0.25 to 50 mg.

15. Use according to claim 14, wherein said amount lies within the range of 0.5 to 40 mg.

16. A kit having utility in treating insomnia patients, which comprises:
(A) a first pharmaceutical formulation in unit dosage form comprising, in addition to at least one diluent, carrier or adjuvant, at least one first active ingredient selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; and
(B) a second pharmaceutical formulation in unit dosage form comprising, in addition to at least one diluent, carrier or adjuvant, at least one second active ingredient selected from nicotine and nicotine receptor agonists;
wherein the dosage units in (A) and (B) are independently selected from those adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration.

17. A kit according to claim 16, which is further characterized by at least one of the following features:
(α) at least one of (A) and (B) is a controlled, sustained or prolonged release formulation;
(β) at least one of (A) and (B) is in a depot form which will release the said active ingredients slowly in the body, over a preselected time period;
(γ) said at least one first active ingredient comprises melatonin;
(δ) said at least one second active ingredient comprises nicotine;
(ε) (A) comprises also at least one melatonin receptor modifier and/or melatonin profile modifier;
(ζ) (A) comprises also at least one further active ingredient selected from nicotine and nicotine receptor agonists;
(η) said first and second active ingredients, and said further active ingredient if present, are present in said dosage units in an amount which lies within the range of 0.025-100 mg.

18. A kit according to claim 17, wherein said first and second active ingredients, and said further active ingredient if present, are present in said dosage units in an amount which lies within the range of 0.25 to 50 mg.

19. A kit according to claim 18, wherein said first and second active ingredients, and said further active ingredient if present, are present in said dosage units in an amount which lies within the range of 0.5 to 40 mg.

20. A kit according to any one of claims 16 to 19, wherein (A) and (B) are each in the form of a transdermal patch.

21. A kit according to any one of claims 16 to 19, wherein (A) is in the form of a controlled release tablet for oral administration and (B) is in the form of a transdermal patch.